

# **EXHIBIT 68**

**EXHIBIT FILED UNDER SEAL**

**Date:** Friday, August 9 2019 01:57 AM  
**Subject:** Re: {Unverified} Regulatory guidance on JUUL proposed inhalation studies  
**From:** RValani@gacapital.com  
**To:** Crosthwaite, Kevin C. Jr KC (ALG) <Kevin.C.Crosthwaite@altria.com>;  
**CC:** Zach Frankel [REDACTED]

Juul Labs, Inc.  
EXHIBIT

**ZF 17781**

7/28/2021 ph

Of course. Please let us know where you end up, and if/how we should engage to get to the right result. On Aug 8, 2019, at 17:29, Crosthwaite, Kevin C. Jr KC (ALG) <[Kevin.C.Crosthwaite@altria.com](mailto:Kevin.C.Crosthwaite@altria.com)> wrote:

Pls do not send this note to JUUL management.

I will push Kevin to engage with Joe and hear his argument. I agree with Joe on his position and it should be debated with someone other than Joanna before this decision is made.

Sent from my iPhone  
Begin forwarded message:

**From:** "Crosthwaite, Kevin C. Jr \"KC\" (ALG)" <[Kevin.C.Crosthwaite@altria.com](mailto:Kevin.C.Crosthwaite@altria.com)>  
**Date:** August 8, 2019 at 2:15:51 PM EDT  
**To:** "[kburns@juul.com](mailto:kburns@juul.com)" <[kburns@juul.com](mailto:kburns@juul.com)>  
**Subject:** FW: {Unverified} Regulatory guidance on JUUL proposed inhalation studies

Might be worth you hearing directly from Joe on this difference of opinion.

**From:** Murillo, Jose Luis (ALCS)  
**Sent:** Thursday, August 8, 2019 1:02 PM  
**To:** Joanna Engelke <[jengelke@juul.com](mailto:jengelke@juul.com)>; Ashley Gould <[ashleygould@juul.com](mailto:ashleygould@juul.com)>  
**Subject:** FW: {Unverified} Regulatory guidance on JUUL proposed inhalation studies

Good morning.

We received this note today. First, I acknowledge this is your call, not ours. However, I want to make clear that we think it is the wrong call, and adds significant risk to your chances of getting a PMTA. I won't regurgitate all of the arguments we have had on this point, but suffice it to say that we do not believe the FDA will accept a risk assessment, or any tox conclusions as to the candidate products, without product testing. We embrace the tool box approach for development and assessment purposes, but at some point, and given the time constraints, product testing needs to be part of the equation. Moreover, we need the FDA to consider our product-based individual risk reduction as a "slam dunk", given the difficulties we will face on the population effects part of the analysis.

I will also say that this is not what I thought we had agreed to do. The flip-flopping on this point over the last few months is of concern from a program management standpoint, especially given the crazy timelines we need to meet.

**From:** Lee, Kyeonghee M. "Monica" (ALCS)  
**Sent:** Thursday, August 8, 2019 9:03 AM

**To:** Murillo, Jose Luis (ALCS) <Joe.Murillo@altria.com>; Gogova, Maria (ALCS) <Maria.Gogova@altria.com>; Smith, Donna C. (ALCS) <Donna.C.Smith@altria.com>; Gardner, William P. "Bill" (ALCS) <William.P.Gardner@altria.com>; Copeland, Elizabeth J. (ALCS) <Elizabeth.J.Copeland@altria.com>  
**Cc:** Ehman, Kimberly D. (ALCS) <Kimberly.D.Ehman@altria.com>; Zhang, Jingjie (ALCS) <Jingjie.Zhang@altria.com>  
**Subject:** FW: {Unverified} Regulatory guidance on JUUL proposed inhalation studies

## **Confidential**

To all: Below is Willie's decision on removing PMTA product in vivo testing.  
 Attached is what was presented by Dimitrios yesterday – The studies he was referring are on Slide-3.

Monica

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**From:** Willie McKinney <willie.mckinney@juul.com>  
**Sent:** Thursday, August 8, 2019 7:34 AM  
**To:** Dimitrios Zisoulis <dimitrios@juul.com>; guy.lalonde@juul.com; pbarone@juul.com; Lee, Kyeonghee M. "Monica" (ALCS) <Kyeonghee.M.Lee@altria.com>; dimitrios@juul.com; shuang.liu@juul.com; jie@juul.com; guy.lalonde@juul.com; adesouza@juul.com; Hockey, Annie (Robertson) <Annie.Hockey@bain.com>  
**Cc:** Josh Vose <jvose@juul.com>; Joanna D Engelke <[REDACTED]>  
**Subject:** {Unverified} Regulatory guidance on JUUL proposed inhalation studies

Dear All

I have listened to the many debates about the studies we plan to conduct. I greatly appreciate the passion and contribution of the team. I know the team is ready to get started, so I am providing clear guidance on what studies to conduct for the PMTA.

When designing the inhalation studies, we must consider three factors.

- the need to ensure that the **ingredients** used in our product are appropriate for their intended use
  - [ML: this doesn't work for PMTA. RA team can't defend ingredients based on risk assessment (NFCs, Altria's toolbox not enough). Therefore the Altria's way of approving ingredients before product release does not work for JUUL
- FDA guidance on animal testing -refinement, reduction, replacement (see below)
- the need to provide consumers acceptable alternatives to cigarettes.

Based on the factors listed above, I provide regulatory guidance on the proposed inhalation studies to be included in the PMTA.

- Test-1 Not needed. Mango ingredients are tested in study 4 (reduction)
- Test-2 Use any delivery system that will deliver the appropriate concentration without clogging. Why is the CAG clogging with this formulation? **Start now. This study is a priority**
- Test 3 Not needed. Mint ingredients are tested in study 5 (reduction)
- Test 4 Start study
- Test 5 Start study

I look forward to seeing the protocols.

Take Care

Willie J. McKinney, Ph.D., D.A.B.T  
Vice President, Global Regulatory Affairs

Junol Labs | 560 20th Street, San Francisco, CA 94107 |

- FDA supports reducing, replacing, and/or refining the use of animal testing in research where adequate and scientifically valid non-animal alternatives can be substituted. FDA encourages sponsors to meet with CTP early in the development process to discuss the suitability and acceptability of non-animal tests for their particular new tobacco product. When animal-based nonclinical laboratory studies are conducted, investigators should use appropriate animal models, adhering to the best practices of refinement, reduction, and replacement of animals in research and following the applicable laws and regulations governing animal testing. (ENDS Guidance)